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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,576	02/11/2004	Krzysztof Sowinski	S63.2-14461-US02	2790

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EXAMINER
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BUTLER, PATRICK NEAL

ART UNIT	PAPER NUMBER
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1791

MAIL DATE	DELIVERY MODE
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02/04/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/776,576	<b>Applicant(s)</b> SOWINSKI ET AL.	
	<b>Examiner</b> Patrick Butler	<b>Art Unit</b> 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-11 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-11,14-16 and 18-20 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20091014</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 16, and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 7,524,445 B2 in view of Edwin et al. (US Patent No. 6,039,755)

With respect to instant Claims 1, 16, and 18, Claim 6 of U.S. Patent No. 7,524,445 B2 claims providing an ePTFE tube, longitudinally expanding the tube, and transversely expanding the tube.

U.S. Patent No. 7,524,445 B2 does not expressly claim expanding the tube using a radially expanding mechanism to apply outward pressure to the inside of the ePTFE tube.

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Edwin teaches radially expanding the tubes around an angioplasty balloon catheter and that longitudinal foreshortening of 1.5-4.7% occurs in samples of IMPRA Lot 34391 (placing said expanded polytetrafluoroethylene tube circumferentially exterior to a longitudinal foreshortening and radially expanding mechanism; applying radial pressure from the longitudinal foreshortening and radially expanding mechanism; radially expanding and longitudinal foreshortening said expanded polytetrafluoroethylene tube over said longitudinal foreshortening and radially expanding mechanism by using said mechanism to apply an outwardly directed force to said luminal surface of said polytetrafluoroethylene tube) (see col. 18, l. 65 through col. 19, l. 31 and col. 20, ll. 1-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Edwin's process of radially expanding and longitudinal foreshortening in the process of U.S. Patent No. 7,524,445 B2 in order to test for radial expansion (see Edwin col. 18, l. 65 through col. 19, l. 31 and col. 20, ll. 1-30).

The nodes and fibrils would have the same shape as claimed principally because the cited claims of U.S. Patent No. 7,524,445 B2 in view of U.S. Patent No. 7,524,445 B2 teach the same process steps.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-11, 14-16, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwin et al. (US Patent No. 6,039,755).

With respect to Claim 1, Edwin teaches extruding a PTFE tube (forming a tube of polytetrafluoroethylene having a luminal surface and an abluminal surface) (see col. 14, l. 59 through col. 14, l. 19) and longitudinal expanding the tubular PTFE extrudate (longitudinally stretching said polytetrafluoroethylene tube to form an expanded polytetrafluoroethylene tube, wherein said expanded polytetrafluoroethylene tube is comprised of fibrils having a first length and oriented in a longitudinal direction of said expanded polytetrafluoroethylene tube and nodes having a first length and oriented in a circumferential direction of said expanded polytetrafluoroethylene tube) (see col. 14, ll. 16-44). Edwin teaches radially expanding the tubes around an angioplasty balloon catheter and that longitudinal foreshortening of 1.5-4.7% occurs in samples of IMPRA Lot 34391 (placing said expanded polytetrafluoroethylene tube circumferentially exterior to a longitudinal foreshortening and radially expanding mechanism; applying radial pressure from the longitudinal foreshortening and radially expanding mechanism; radially expanding and longitudinal foreshortening said expanded polytetrafluoroethylene tube over said longitudinal foreshortening and radially expanding mechanism by using said mechanism to apply an outwardly directed force to said luminal surface of said polytetrafluoroethylene tube) (see col. 18, l. 65 through col. 19, l. 31 and col. 20, ll. 1-30). Regarding the claimed limitations of consistent fibril length between longitudinal and radial expansion and the claimed limitation of node lengthening between longitudinal and radial expansion, Edwin teaches that the nodes,

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rather than fibrils, lengthen during the radial expansion due to the longitudinal direction of the nodes (see col. 12, lines 13-67). The claimed limitation of hingeably rotating the fibrils, Edwin's node-to-node fibril path rotates from the original tubular longitudinal direction in a tangled or tortuous path (see col. 12, lines 13-67). Moreover, the claimed fibril and node properties are achieved by Edwin principally because Edwin teaches the same steps as claimed.

With respect to Claim 2, Edwin teaches radially expanding the tubes around an angioplasty balloon catheter at 37 °C (99 °F) (said expanding polytetrafluoroethylene tube is heated to a temperature of between about 86 and 650 °F during the radially expanding and longitudinal foreshortening step) (see col. 19, ll. 19-29).

With respect to Claim 5, the fibrils' shape would stay the same principally because they are within the same tube as claimed and subjected to the same steps as claimed.

With respect to Claims 6-11, Edwin's method of making a PTFE tube would result in a final tubular structure whose longitudinal (Claims 6-8) and radial (Claims 9-11) expansion properties are as claimed principally because Edwin's method uses the same steps as claimed to achieve the final structure. Moreover, Edwin teaches radially expanding the balloons 3 and 5 times and up to 700%, which would provide the balloon having 3x expansion with at least 1.7x or 2.3x additional expansion (Claim 9: capable of radially expanded by at least a factor of 1.5; Claim 10: capable of radially expanded by at least a factor of 2.0) (see col. 9, ll. 30-45 and col. 15, ll. 34-40)).

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With respect to Claim 14, Edwin teaches sintering the PTFE extrudate (see col. 15, ll. 13-33).

With respect to Claim 15, Edwin's heating step would affect the tube's structural integrity as claimed principally because Edwin's method uses the same steps as claimed to achieve the final structure.

With respect to Claim 16, Edwin teaches making a PTFE tube as applied to Claim 1 above. Moreover, Edwin teaches radially expanding the tubes around an angioplasty balloon catheter at 37 °C (99 °F) (heating said expanded polytetrafluoroethylene tube to a temperature of between about 86 and 650 °F during radial expansion) (see col. 19, ll. 19-29).

With respect to Claim 18, Edwin teaches making an ePTFE tube as applied to Claim 1 above. Edwin's method of making an ePTFE tube would result in a final tubular structure with reoriented fibrils whose nodal orientation has a greater length between said nodes as compared to said expanded polytetrafluoroethylene tube principally because Edwin's method uses the same steps as claimed to achieve the final structure.

With respect to Claim 19, Edwin teaches radially expanding the tubes around an angioplasty balloon catheter at 37 °C (99 °F) (heating said expanded polytetrafluoroethylene tube to a temperature of between about 86 and 650 °F during radial expansion) (see col. 19, ll. 19-29).

With respect to Claim 20, Edwin's method of making an ePTFE tube would result in a final tubular structure whose reoriented fibrils are longitudinally straighter than said

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fibrils of said expanded polytetrafluoroethylene tube principally because Edwin's method uses the same steps as claimed to achieve the final structure.

### ***Allowable Subject Matter***

Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach or suggest the claimed process of radially expanding longitudinally expanded polytetrafluoroethylene tube at a temperature of about 200 °F and 350 °F. Instead, Edwin et al. (US Patent No. 6,039,755) teaches radially expanding the tubes around an angioplasty balloon catheter at 37 °C (99 °F) (see col. 19, ll. 19-29) to test radial expansion when implanted in a body (see col. 1, ll. 7-17).

### ***Response to Arguments***

Applicant's arguments filed 01 July 2009 have been fully considered, but they are not persuasive.

Applicant argues with respect to the 35 U.S.C. § 102(b) rejections. Applicant's arguments appear to be on the grounds that:

1) House does not teach radial expansion against the inner side of the EPTFE structure.

The Applicant's arguments are addressed as follows:



1) Applicant's arguments with respect to the newly claimed limitation of radial expansion against the inner side of the EPTFE structure have been considered but are moot in view of the new ground(s) of rejection over Edwin et al. (US Patent No. 6,039,755) as recited above.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Butler whose telephone number is (571) 272-8517. The examiner can normally be reached on Mon.-Thu. 7:30 a.m.-5 p.m. and alternating Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. B./

Examiner, Art Unit 1791

/Christina Johnson/

Supervisory Patent Examiner, Art Unit 1791